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(71) Applicant: **Terumo Kabushiki Kaisha**
No. 44-1, Hatagaya 2-chome Shibuya-ku
Tokyo 151(JP)

(72) Inventor: **TSUCHIDA, Kouji**
Terumo Kabushiki Kaisha 2656-1, Ohbuchi
Fuji-shi Shizuoka-ken 417(JP)
Inventor: **ISHITSU, Yoshio**
Terumo Kabushiki Kaisha 2656-1, Ohbuchi
Fuji-shi Shizuoka-ken 417(JP)
Inventor: **SEKII, Shigekazu**
Terumo Kabushiki Kaisha 2656-1, Ohbuchi
Fuji-shi Shizuoka-ken 417(JP)

(74) Representative: **Casalonga, Axel et al**
BUREAU D.A. CASALONGA - JOSSE
Morassistrasse 8
D-8000 München 5(DE)

(54) **MULTI-LUMINAL CATHETER, MULTI-LUMINAL CATHETER ASSEMBLY AND PRODUCTION THEREOF.**

EP 0 366 794 A1
(57) A multi-luminal catheter of this invention is characterized in that the cross-sectional shape of each lumen at a connection portion for an extension tube is molded in advance to the outer shape of the extension tube to be connected. Accordingly, smooth and hermetic connection between a catheter body and the extension tube, that has not been accomplished in the past, can be obtained, and the formation of steps of the lumen which increases fluid resistance can be prevented. This multi-luminal catheter can be produced by pressing a core metal having substantially the same shape as that of the outer shape of the extension tube into each lumen of the catheter body at the connection portion for the

extension tube and inserting the core metal into a molding die while heating it. Higher air-tightness and connection strength can be obtained by fitting the connection end of the extension tube into each lumen at the connection portion of the multi-luminal catheter and integrating them by use of a fixing member.

TITLE MC
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S P E C I F I C A T I O N

Multi-luminal catheter, multi-luminal catheter
assembly, and method of manufacture

[Technical Field]

This invention concerns a multi-luminal catheter wherein the lumens of the catheter, which have a different shape to the external form of the extension tubes to be connected to them, are given a shape which corresponds to said external form of said extension tubes at the extension tube connectors. It also concerns a method of manufacturing said catheter.

Further, this invention concerns a multi-luminal catheter assembly comprising a catheter body with multiple lumen, extension tubes connected to said catheter and members for fastening the catheter body and the extension tubes together, and a method of manufacturing said assembly.

15 [Background Art]

In order to make most effective use of the volume of the cavities in a multi-luminal catheter, their cross-section is generally not circular, as shown in Fig. 1(b). The cross-sections of the extension tubes to be connected to the catheter body on the other hand are circular, and if these tubes are connected to the catheter without modification, airtight connections are consequently not obtained. Further, even when the cross-sections of both the catheter lumens and

extension tubes are circular, the diameters of the extension tube lumens must necessarily be made smaller to insert the tubes into the catheter lumens. For this reason, a differential arises between the lumens, and gives rise to problems such as increased fluid resistance.

Conventionally, this problem was solved by making the connection through molded pieces of the same shape as the lumens, or by filling the spaces between the catheter lumens and the outer circumference of the extension tubes with adhesive.

If connections were made through molded pieces of the same shape as the catheter lumens, however, the manufacturing cost increased undesirably. If on the other hand the spaces between the inner surfaces of the catheter lumens and extension tubes were filled with adhesive, it was still difficult to obtain a perfectly airtight seal.

Further, in multi-luminal catheters manufactured by the above methods, the joint strength between the catheter body and the extension tubes is inadequate, and the tubes easily fall out of the catheter body in actual use.

This invention therefore aims to provide a multi-luminal catheter wherein extension tubes can be connected easily to the catheter body, and good airtightness is obtained.

[Disclosure of the Invention]

The multi-luminal catheter of this invention is characterized in that it has lumens of substantially the same shape as the ends of the extension tubes to be connected to the tube connectors of the catheter body, which consists of thermoplastic resin and has multiple lumens of different shape to the external form of said tubes.

As the shapes of the lumens at the extension tube connectors in this multi-luminal catheter, are

substantially identical to the external form of said tubes, the tube connections can be made smoothly, and airtight connections can be obtained. Further, even when the cross-sections of both the catheter lumens and extension tube lumens are circular, it is possible to connect extension tubes of substantially similar diameter to the catheter lumens, and increased fluid resistance of the lumens can thus be avoided.

This invention also aims to provide a method of manufacturing said multi-luminal catheter. In this method, cores of substantially similar form to the ends of the extension tube are pressed into the extension tube connectors of the catheter body, which consists of thermoplastic resin and has multiple lumens of different form to the extension tubes. The positions where the cores have been pressed into the catheter body are then heated, softened and introduced into a mold so as to create voids corresponding to the external form of the cores when the cores are subsequently withdrawn. Finally, the core insertion positions are cooled, and the cores are withdrawn.

In this method, as the multi-luminal catheter with extension tube connectors is made in such a way that the connector openings have identical shapes to the external form of the tube connecting ends, the tube connections can be made smoothly, and airtight connections can be obtained.

In molding the extension tube connector of the catheter body by said heat molding process, it is preferable if the parts to be molded are first pre-heated to the softening temperature, and then introduced into the mold while applying heat in stages.

This invention also aims to provide a multi-luminal catheter assembly comprising a multi-luminal catheter body wherein said extension tube connectors are first shaped to correspond to the external form of the ends of extension tubes, several extension tubes of which the

ends are inserted into the connectors of said catheter body, and fixing members which entirely cover the connectors between said catheter body and said extension tubes, and part of the catheter body and the extension tubes near these connectors.

In this multi-luminal catheter assembly, after the catheter body and the extension tubes are connected, the connectors are fixed en bloc by covering them with a fixing member. As a result, better airtightness and joint strength are obtained than in the case where said multi-luminal catheter is used alone.

Further, this invention aims to provide a method of manufacturing said multi-luminal catheter assembly. In this method, the connecting ends of several extension tubes are inserted and fixed in the lumens of the catheter body wherein the tube connectors have been shaped to fit the external form of the tube ends, following which said catheter body, said extension tube connectors, and the part of the catheter body and part of the extension tubes near the connectors, are entirely covered with a fixing member.

In this method, said fixing member may consist only of adhesive, or it may consist of an outer casing and a filler filling the space inside the outer casing. Further, said outer casing may consist of a casing body with the form of a tube, and a cap connected to the open end of the casing.

[Brief Description of the Drawings]

Fig. 1(a) is a sectional view of the base of the multi-luminal catheter;

Fig. 1(b) is a sectional view taken along the line -- in Fig. 1(a);

Fig. 2(a) is a sectional view of the molding mechanism which explains the method of manufacturing the multi-luminal catheter of this invention;

Fig. 2(b) is a sectional view taken along the line -- in Fig. 2(a);

Fig. 3(a) is a sectional view of the molding mechanism which explains the processes following Fig. 2(a);

5 Fig. 3(b) is a sectional view taken along the line -- in Fig. 3(a);

Fig. 4 is a partial sectional view showing the catheter body connected with the extension tubes; and

Fig. 5 is a partial sectional view showing a multi-luminal catheter in one embodiment of this invention.
10 [Best Mode of Carrying Out the Invention]

We shall now explain embodiments of this invention with reference to the drawings.

First, as shown in Fig. 1(a), the catheter body 1 is formed comprising a main part 1a of specified shape,
15 and a flared base 1b with a taper for connecting extension tubes. This catheter body may be formed by any convenient method. It should however preferably be formed continuously by extrusion molding with control of resin discharge, stretching rate and internal pressure
20 of the lumens, and then cut into desired lengths. In this way, a catheter body 1 with 4 lumens 2a - 2d of non-circuit cross-section as shown in Fig. 1b is obtained.

The thermoplastic material of catheter body 1 may
25 be one of the conventional resins such as polyvinyl chloride, polyurethane, silicone resin and ethylene-vinyl acetate copolymer (EVA).

Next, as shown in Figs. 2a and 2b, cores 4 of substantially similar form to the extension tube 3 that is
30 to be connected (see Fig. 4), are pressed into lumens 2a - 2d to the necessary depth. Cores 4 should preferably consist of brass or stainless steel.

Subsequently, only the part of the catheter body 1 into which cores 4 have been inserted, is introduced
35 into mold 5 and heated by hot air. The heating temperature should preferably be sufficient to slightly soften the catheter body 1. If the catheter body 1 is of

polyvinyl chloride, this temperature is approx. 40 - 90°C. The mold may be any of the molds normally used, but should preferably be of stainless steel if the cooling is done by means of water.

5 The heating carried out to raise the catheter body 1 to the softening temperature may be carried out before introducing it into mold 5, following which the catheter body 1 may be introduced into mold 5 while continuing the heating. Further, apart from hot air, the heating
10 may be effected by a heating wire, ultrasonic waves, high frequencies or a combination of any of these methods.

 The catheter body 1 is then pulled into the mold 5 while heating that part (flared base) 1b of body 1 which
15 is to be molded. The pulling of body 1 is temporarily stopped when its end 1c is 5 - 20 mm in front of the entrance 5a of mold 5, and the part 1b is then heated to a higher temperature. This temperature should be high enough to fully deform the part 1b, and if the catheter
20 body 1 is of polyvinyl chloride, for example, it should preferably be approx. 100 - 150°.

 When the part 1b to be molded has reached the deformation temperature, the catheter body 1 is pulled completely into mold 5, and heating is continued for a
25 further 1 - 2 minutes. In this way, circular openings 2e - 2h identical to the shape of cores 4 will be formed in the connecting end of catheter body 1 when the cores are removed (see Fig. 3b).

 Subsequently, mold 5 is cooled by means of air or
30 water cooling, the catheter body 1 is removed from mold 5, and cores 4 are removed from openings 2e - 2h to complete the molding process.

 In this way, by separating the heating of the part 1b of catheter body 1 to be molded into several stages,
35 the optimum temperatures for pulling the body 1 in and for molding can be selected, and the molding process can proceed smoothly.

As the lumens 2e - 2h of catheter body 1 molded by the above process, are identical to the external form of the extension tubes, the extension tubes can be inserted in smoothly and airtight connections can be obtained.

5 The connection of extension tubes 3 to lumens 2e - 2h of catheter body 1 can be made by pushing the tubes 3 coated with adhesive into the lumens 2e - 2h, and hardening the adhesive (see Fig. 4). Examples of
10 adhesives that can be used are epoxy adhesives, polyurethane adhesives, acrylic adhesives, EVA adhesives, silicone adhesives and phenolic adhesives, a suitable adhesive being chosen from this list. Further, apart from said adhesive method, the connection may be made by solvent welding with solvents such as ketones, esters,
15 chlorinated carbon or aromatic hydrocarbons, by ultrasonic fusion, or by high frequency fusion.

The connection between said multi-luminal catheter and extension tubes has far superior airtightness and joint strength to conventional multi-luminal catheters,
20 and if a fixing member is used to cover the connections between catheter body 1 and extension tubes 3, and the area near the connections, even better airtightness and joint strength can be obtained.

Fig. 5 shows an embodiment of a multi-luminal
25 catheter assembly using such a fixing member. As shown in Fig. 5, the area near the connector of the catheter body 1 with extension tubes 3 connected, is covered by a casing body 7 of which part has an inner diameter larger than the external diameter of the flared base 1b
30 of catheter body 1, and the space between the casing body and the catheter body is filled with a resin 8 for filling. A cap 9 penetrated with extension tube 3 is then pushed into the open end of the casing body 7, and joined to the casing 7 by means of adhesive, ultrasonic
35 waves or high frequency waves so as to complete the assembly. In the multi-luminal catheter assembly so obtained, the connector between the catheter body 1

and extension tubes 3, and the neighboring part of the catheter and the extension tubes are entirely covered, so the joint has improved airtightness and strength than if the catheter body 1 were used alone.

5 Any material may be used for the casing body 7 provided it has the required strength, suitable examples being polycarbonate, polypropylene, ABS resin and polyvinyl chloride. Further, the filler 8 used to fill the casing body 7 may be an epoxy resin, silicone resin,
10 polyurethane resin, acrylic resin, EVA resin, phenolic resin or vinyl chloride resin.

 In the above example, both casing body 7 and cap 9 are used as fixing members. In the multi-luminal catheter assembly of this invention, however, instead of this
15 arrangement, the catheter body may for example be covered and fixed by an outer casing of one piece construction not separated into a casing body and cap, or simply by a layer of adhesive without using an outer casing.

Claims:

1. A multi-luminal catheter characterized in that openings are formed at extension tube connectors of a catheter body which consists of thermoplastic material and has multiple lumens of different shape to the external form of extension tubes to be connected to the extension tube connectors, and the openings have the same shape as the ends of the extension tubes.

2. A multi-luminal catheter as in claim 1, wherein the thermoplastic material is polyvinyl chloride.

3. A method of manufacturing a multi-luminal catheter, wherein cores of substantially similar external form to the ends of the extension tube to be connected to a catheter body are inserted into connectors of the catheter body which consists of thermoplastic material and has multiple lumens of different form to the extension tubes, the connectors whereinto the cores have been inserted then being heated, softened and introduced into a mold so as to create openings corresponding to the external form of the cores, the core insertion positions then being cooled, and the cores withdrawn.

4. A manufacturing method as in claim 3, wherein said connectors into which cores have been inserted are first heated to the softening temperature of the catheter body before introducing them into the mold, and are then introduced into the mold while applying heat in stages.

5. A manufacturing method as in claim 4, wherein the parts of the catheter body to be molded are first heated to the softening temperature of the catheter body before introducing the connectors into the mold or after they have been partially introduced, cores having been inserted into the connectors, said parts to be molded are then partially introduced into said mold and heated to a temperature sufficient to deform the catheter body,

and substantially the whole of said connectors is then introduced into said mold, molded and cooled so as to form lumens.

5 6. A manufacturing method as in claim 3, wherein the heating of the catheter body is effected by means of hot air, heating wire, ultrasonic waves or high frequency, or by a combination of these techniques.

10 7. A multi-luminal catheter assembly characterized in that it comprises a multi-luminal catheter body having multiple lumens at extension tube connectors, the lumens first being shaped to correspond to the external form of the connecting ends of the extension tubes to be connected to said connectors, several extension tubes of which the ends are inserted into the lumens of the connectors of said catheter body, and a fixing member which
15 entirely covers the connectors between said catheter body and said extension tubes, and part of the catheter body and the extension tubes near these connectors.

20 8. A multi-luminal catheter assembly as in claim 7, wherein said fixing member is comprised only of an adhesive layer.

25 9. A multi-luminal catheter assembly as in claim 7, wherein said fixing member contains an outer casing and a filler filled inside the outer casing.

30 10. A multi-luminal catheter assembly as in claim 9, wherein said outer casing contains a casing body, and a cap connected to the open end of the casing body.

35 11. A multi-luminal catheter assembly as in claim 8, wherein said filler is at least one type of synthetic resin chosen from the group consisting of epoxy resin, silicon resin, polyurethane resin, acrylic resin, ethylene-vinyl acetate copolymer, phenolic resin and vinyl chloride resin.

40 12. A multi-luminal catheter assembly as in claim 9, wherein the extension tubes are secured to the lumens of the catheter body by means of solvent

welding.

13. A multi-luminal catheter assembly as in claim 12, wherein said solvent is a ketone, ester, chlorinated hydrocarbon or aromatic hydrocarbon.

5 14. A multi-luminal catheter assembly as in claim 8 or 9, wherein the extension tubes are secured to the lumens in the connectors of the catheter body by an adhesive.

10 15. A multi-luminal catheter assembly as in claim 14, wherein said adhesive is of the epoxy, polyurethane, acrylic, ethylene-vinyl acetate copolymer, silicon or phenolic type.

15 16. A multi-luminal catheter assembly as in claim 8 or 9, wherein the extension tubes are secured to the lumens of the connectors of the catheter body by means of heat fusion with a heating means.

20 17. A method of manufacturing a multi-luminal catheter assembly characterized by inserting connecting ends of several extension tubes respectively into multiple lumens of connectors to which the tubes are to be connected, the lumens first being shaped to correspond to the external form of the connecting ends of the extension tubes, then securing the extension tubes, and entirely covering the connectors between said catheter
25 body and said extension tubes, and part of the catheter body and the extension tubes near these connectors by a fixing member.

30 18. A method of manufacturing a multi-luminal catheter as in claim 17, wherein said fixing member is comprised only of an adhesive.

35 19. A method of manufacturing a multi-luminal catheter as in claim 17, wherein said fixing member comprises an outer casing and a filler filled inside the casing, and the space between the casing, outer surface of the catheter body and outer surface of the extension tubes being filled with the filler after inserting the catheter body into said casing.

20. A method of manufacturing a multi-luminal catheter as in claim 19, wherein said outer casing comprises a casing body and a cap connected to its open end, and the cap being connected to the casing body after filling the space between the casing body, outer surface of the catheter body and outer surface of the extension tubes with adhesive.

5

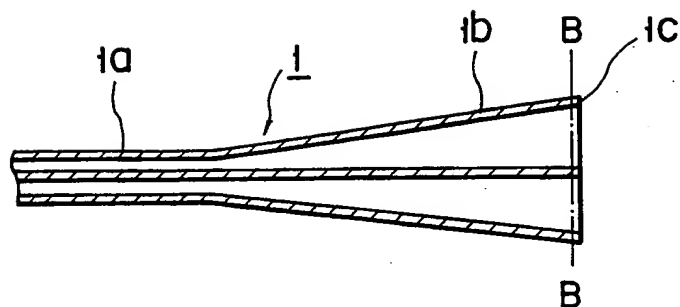


FIG. 1a

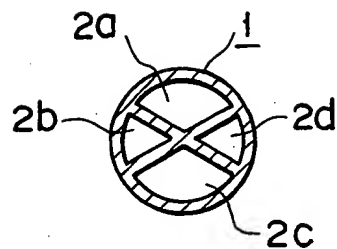


FIG. 1b

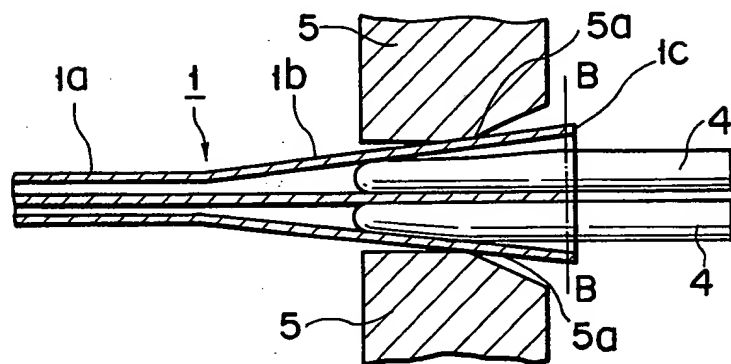


FIG. 2a

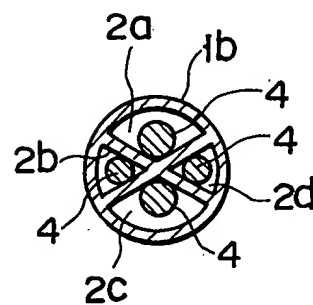


FIG. 2b

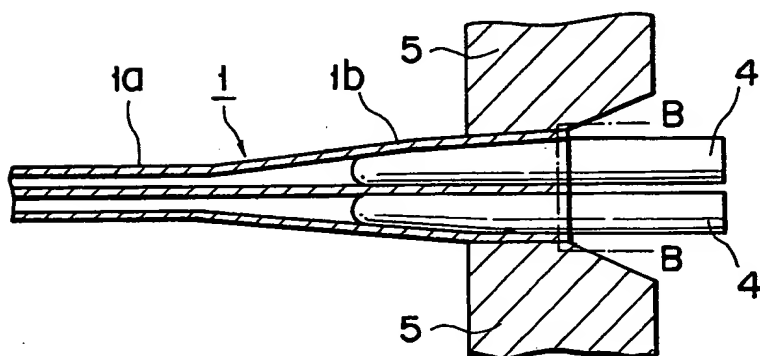


FIG. 3a

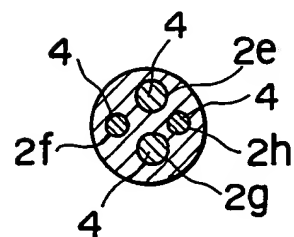


FIG. 3b

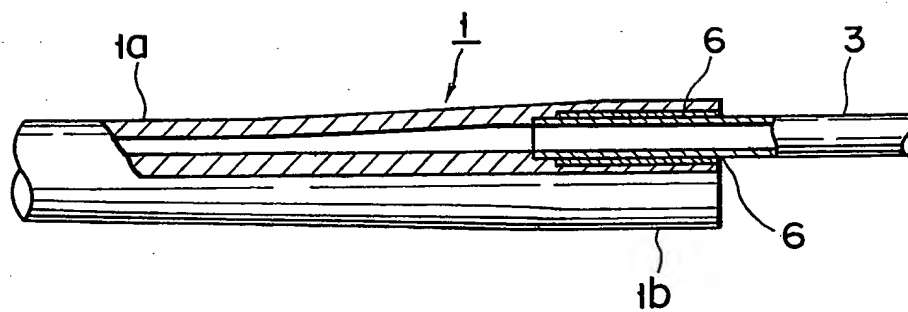


FIG. 4

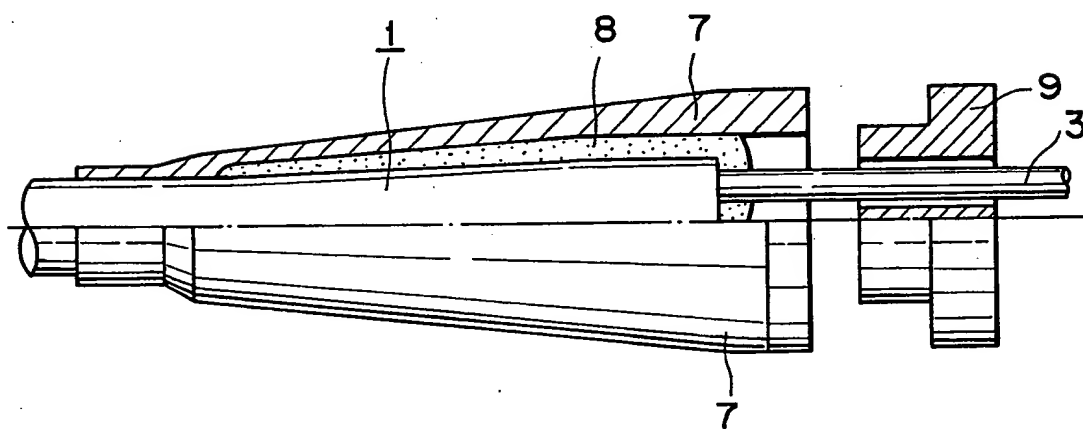


FIG. 5

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INTERNATIONAL SEARCH REPORT

International Application No PCT/JP88/00634

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁴ According to International Patent Classification (IPC) or to both National Classification and IPC <div style="text-align: center; font-size: 1.2em;">Int.Cl⁴ A61M25/00</div>											
II. FIELDS SEARCHED <div style="text-align: center; font-size: 0.8em;">Minimum Documentation Searched ¹</div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; padding: 5px;">Classification System</td> <td style="padding: 5px;">Classification Symbols</td> </tr> <tr> <td style="text-align: center; padding: 10px;">IPC</td> <td style="padding: 10px;">A61M25/00, 5/14, B29C65/02</td> </tr> </table>			Classification System	Classification Symbols	IPC	A61M25/00, 5/14, B29C65/02					
Classification System	Classification Symbols										
IPC	A61M25/00, 5/14, B29C65/02										
<div style="text-align: center; font-size: 0.8em;">Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched ⁴</div> <table style="width: 100%;"> <tr> <td style="width: 60%;">Jitsuyo Shinan Koho</td> <td style="text-align: right;">1955 - 1988</td> </tr> <tr> <td>Kokai Jitsuyo Shinan Koho</td> <td style="text-align: right;">1971 - 1988</td> </tr> </table>			Jitsuyo Shinan Koho	1955 - 1988	Kokai Jitsuyo Shinan Koho	1971 - 1988					
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III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹ <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 10%; padding: 5px;">Category ⁸</th> <th style="width: 70%; padding: 5px;">Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²</th> <th style="width: 20%; padding: 5px;">Relevant to Claim No. ¹³</th> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 10px;">X</td> <td style="padding: 10px;">JP, A, 60-241453 (Warnar - Lambert Company) 4 December 1985 (04. 12. 85) Page 9 & EP, A2, 161863</td> <td style="text-align: center; vertical-align: top; padding: 10px;">1-2, 7-16</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 10px;">X</td> <td style="padding: 10px;">JP, A, 60-244527 (Warnar - Lambert Company) 4 December 1985 (04. 12. 85) Page 10 & EP, A2, 161862</td> <td style="text-align: center; vertical-align: top; padding: 10px;">3-6, 17</td> </tr> </table>			Category ⁸	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³	X	JP, A, 60-241453 (Warnar - Lambert Company) 4 December 1985 (04. 12. 85) Page 9 & EP, A2, 161863	1-2, 7-16	X	JP, A, 60-244527 (Warnar - Lambert Company) 4 December 1985 (04. 12. 85) Page 10 & EP, A2, 161862	3-6, 17
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<div style="font-size: 0.8em;"> <div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <p>¹⁰ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 48%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"Z" document member of the same patent family</p> </div> </div> </div>											
IV. CERTIFICATION <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;"> Date of the Actual Completion of the International Search <div style="text-align: center; font-size: 1.1em;">August 29, 1988 (29. 08. 88)</div> </td> <td style="width: 50%; padding: 5px;"> Date of Mailing of this International Search Report <div style="text-align: center; font-size: 1.1em;">September 12, 1988 (12. 09. 88)</div> </td> </tr> <tr> <td style="padding: 5px;"> International Searching Authority <div style="text-align: center; font-size: 1.1em;">Japanese Patent Office</div> </td> <td style="padding: 5px;"> Signature of Authorized Officer: </td> </tr> </table>			Date of the Actual Completion of the International Search <div style="text-align: center; font-size: 1.1em;">August 29, 1988 (29. 08. 88)</div>	Date of Mailing of this International Search Report <div style="text-align: center; font-size: 1.1em;">September 12, 1988 (12. 09. 88)</div>	International Searching Authority <div style="text-align: center; font-size: 1.1em;">Japanese Patent Office</div>	Signature of Authorized Officer:					
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